

Practitioner's Docket No. **FAK-8011****PATENT****IN THE UNITED STATES DESIGNATED OFFICE (DO/US)****PCT/AU2004/001006****28 July 2004****28 July 2003**

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

**10/565,616**

U.S. APPLICATION NO.

**SKIN REGENERATION SYSTEM**

TITLE OF INVENTION

**Zee Upton et al.**

APPLICANT(S) FOR DO/US

**Mail Stop PCT****Commissioner for Patents****P.O. Box 1450****Alexandria, VA 22313-1450**

**COMPLETION OF FILING REQUIREMENTS  
FOR INTERNATIONAL APPLICATION ENTERING NATIONAL  
STATE IN U.S. DESIGNATED OFFICE (DO/US) UNDER 35 U.S.C. §371**

(check and complete the following item, if applicable)



This replies to the Notice of Missing Requirements under 35 U.S.C. §371 and 37 C.F.R. § 1.494 (FORM PCT/DO/EO/905)



A copy of FORM PCT/DO/EO/905 accompanies this response.

**WARNING:** Where the items being submitted to complete the entry of the international application into the national phase are filed subsequent to the initial application is still considered to be in the international stage. If mailing procedures are utilized to obtain a date, the express mail procedure of 37 C.F.R. § 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 C.F.R. § 1.8(2)(xi).

**Note:** Documents and fees must be clearly identified as a submission to enter the national stage under 35 U.S.C. § 371. Otherwise, the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(f).

**EXPRESS MAILING UNDER 37 C.F.R. § 1.10\***

(Express Mail label number is mandatory.)

(Express Mail Certification is optional.)

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date June 9, 2006, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EQ-477632985US, addressed to the "Mailstop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450."

  
 Signature
Date: June 9, 2006Anita J. Galo

(type or print name of person certifying)

**WARNING:** Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).  
 "Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

## DECLARATION OR OATH

**NOTE:** 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits...the oath or declaration of the inventor (35 U.S.C. 371(c)4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the ...oath or declaration in order to prevent abandonment of the application....The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."

- I. ☒ No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

### OR

- ☐ The declaration or oath that was filed was determined to be defective. A new original or oath or declaration is attached..

**NOTE:** For surcharge fee for filing declaration after filing date, complete item IV(2).

**NOTE:** Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:

- (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
- (B) serial number and filing date;
- (C) attorney docket number which was on the specification as filed;
- (D) title of the inventor which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
- (E) title of the inventor which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 602, 8<sup>th</sup> ed.

**NOTE:** Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. § 1.10(c).

**NOTE:** 37 C.F.R. § 1.41(a) points out that "Full names must be stated, including the family name and at least one given name without abbreviation together with any other given name or initial."

(complete (a) or (b), if applicable)

Attached is a

- (a) ☐ Statement by a registered attorney that the application filed in the PTO is the application that the inventor executed by signing the declaration.
- (b) ☐ Statement that the "attached" specification is a copy of the specification and any amendments thereto that were filed in the PTO to obtain the filing date.

## AMENDMENT

### II. (complete as applicable)

- ☐ An amendment in accordance with 37 C.F.R. § 1.121 is attached.
- ☐ The attached amendment cancels claims \_\_\_\_\_ inclusively.

## TRANSMITTAL OF ENGLISH TRANSLATION OF NON-ENGLISH LANGUAGE PAPERS

**NOTE:** 37 C.F.R. § 1.495(c): 'If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits...a translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)...applicant will be so notified and given a period of time within which to file the translation...in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of thirty months after the priority date...A 'Sequence Listing' need not be translated if the 'Sequence Listing' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b)'.

- III. ☐ Submitted herewith, is an English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO (See 37 C.F.R. § 1.495(c))

**NOTE:** For fee for processing a non-English application, and submission of an English translation later than 30 months after the priority date, complete item IV(3) below.

**NOTE:** A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 C.F.R. § 1.69(b).

## FEES

### IV.

**NOTE:** See 37 C.F.R. § 1.28(a).

#### 1. Fees for claims

- ☐ Each independent claim in excess of 3  
(37 C.F.R. § 1.492(b)--\$200.00; small entity--\$100.00) \$ \_\_\_\_\_
- ☐ Each claim in excess of 20  
(37 C.F.R. § 1.492(c)--\$50.00; small entity--\$25.00) \$ \_\_\_\_\_
- ☐ Multiple dependent claim(s)  
(37 C.F.R. § 1.492(d)--\$360.00;  
small entity--\$180.00) \$ \_\_\_\_\_

#### 2. Surcharge fees

- ☒ Surcharge for filing the oath or declaration later than  
thirty months from the priority date pursuant to  
§ 1.495(c) and § 1.492(e): \$130.00; small entity--\$65.00 \$ 65.00

**NOTE:** The processing fee in the next item (Number 3) below is not subject to a reduction for small entity status.

3. ☐ For filing an English translation of an international  
application later than thirty months after the  
priority date (§ 1.495(c)) and § 1.492(f): \$130.00 \$ \_\_\_\_\_
4. ☒ Assignment (See "ASSIGNMENT COVER SHEET".) \$ 40.00

Total fees **\$105.00**

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office  
(DO/US) under 35 U.S.C. § 371[13-8]--Page 3 of 6  
Express Mail No. **EQ-477632985US**

06/14/2006 GFREY1 00000131 10565616

01 FC:2617

65.00 DP

### SMALL ENTITY STATUS

- V. ☒ An assertion that this filing is by a small entity

(check and complete applicable items)

- a. ☐ is attached.  
☐ was filed on \_\_\_\_\_ (original).  
☒ was made by paying the basic national filing fee as a small entity.  
☐ is being made now by paying the basic national filing fee as a small entity.
- b. ☐ A separate refund request accompanies this paper.

### EXTENSION OF TIME

(complete (a) or (b), as applicable)

VI.

*NOTE: 37 C.F.R. § 1.704(b)"...an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph."*

The proceedings herein are for a patent application. The provisions of 37 C.F.R. § 1.136(a) apply.

- (a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(1)-(4) for the total number of months checked out below:

| Extension<br>(months)                 | Fee for other than<br><u>small entity</u> | Fee for<br><u>small entity</u> |
|---------------------------------------|---|--------------------------------|
| <input type="checkbox"/> one month    | \$ 120.00                                 | \$ 60.00                       |
| <input type="checkbox"/> two months   | \$ 450.00                                 | \$ 225.00                      |
| <input type="checkbox"/> three months | \$ 1,020.00                               | \$ 510.00                      |
| <input type="checkbox"/> four months  | \$ 1,590.00                               | \$ 795.00                      |
| <input type="checkbox"/> five months  | \$ 2,160.00                               | \$ 1,080.00                    |

Fee \$ \_\_\_\_\_

If an additional extension of time is required, please consider this a petition therefore.

(check and complete the next time, if applicable)

- ☐ An extension for \_\_\_\_\_ months has already been secured and the fee paid therefore of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

or

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

### TOTAL FEE DUE

VII. The total fee due is

|                        |                 |
|------------------------|-----------------|
| Complete fee(s)        | \$105.00        |
| Extension fee (if any) | \$ 0.00         |
| <b>TOTAL FEE DUE</b>   | <b>\$105.00</b> |

### PAYMENT OF FEES

VIII.

- ☒ Attached is a ☒ check ☐ money order in the amount of \$105.00
- ☒ Authorization is hereby made to charge the amount of \$0.00
- ☒ to Deposit Account No. 20-0090.
- ☐ to Credit card as shown on the attached credit card information authorization form PTO-2038.

**WARNING:** Credit card information should **not** be included on this form as it may become public.

- ☐ Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

A duplicate of this transmittal is attached.

### AUTHORIZATION TO CHARGE ADDITIONAL FEES

IX.

**WARNING:** Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.

**NOTE:** "A written request may be submitted in an application that is an authorization to treat any concurrent or future rely, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

**NOTE:** "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

**NOTE:** The previous practice of holding applications abandoned if an authorization to charge fees under 37 C.F.R. § 1.16 has been provided instead of an authorization to charge fees under 37 C.F.R. § 1.492 has been changed. The Office amended 37 C.F.R. § 1.25(b), effective November 7, 2000, so that an authorization to charge fees under 37 C.F.R. § 1.16 in an international application entering the national stage under 35 U.S.C. § 371 is now accepted by the Office as an authorization to charge fees under 37 C.F.R. § 1.492.

☒ Please charge, in the manner authorized above, the following additional fees that may be required by this paper and during the entire pendency of this application:

☒ 37 C.F.R. §§ 1.492(a)(2), 1.492(a)(3), or 1.492(a)(5) (filing fees)

☒ 37 C.F.R. § 1.492(b) (presentation of extra claims)

**NOTE:** Because additional fees for excess or multiple dependent claims not paid on filing, or on later presentation, must only be paid, or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☒ 37 C.F.R. § 1.17 (application processing fees)

☒ 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a))

**WARNING:** While 37 C.F.R. § 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 C.F.R. § 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

**NOTE:** Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application **only after the mailing of the notice of allowance**. Accordingly, general authorizations to pay fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL-85B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1.311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant and submitted, § 1.311(b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b). Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

**NOTE:** 37 C.F.R. § 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application...prior to paying, or at the time of paying...issue fee." From the wording of 37 C.F.R. § 1.28(b):(a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

☐ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or an English translation of an international application later than 20 months from the earliest claimed priority date).

**WARNING:** It is suggested that you always check this last authorization.

  
**SIGNATURE OF PRACTITIONER**

Richard S. Wesorick

(type or print name of attorney)

Reg. No.: 40,871

Tel. No.:(216) 621-2234

Tarolli, Sundheim, Covell  
& Tummino L.L.P.  
1300 East Ninth Street, Suite 1700  
P.O. Address  
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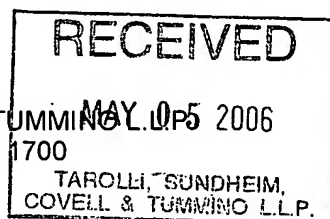
## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

|                             |                       |                  |
|-----------------------------|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/565,616                  | Zee Upton             | FAK8011          |

26294

TAROLLI, SUNDHEIM, COVELL & TUMMINO LLP  
1300 EAST NINTH STREET, SUITE 1700  
CLEVEVLAND, OH 44114



|                               |               |
|-------------------------------|---------------|
| INTERNATIONAL APPLICATION NO. |               |
| PCT/AU04/01006                |               |
| I.A. FILING DATE              | PRIORITY DATE |
| 07/28/2004                    | 07/28/2003    |

CONFIRMATION NO. 2998

371 FORMALITIES LETTER



\*OC000000018664986\*

Date Mailed: 05/02/2006

FAK-8011  
RSW

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 01/24/2006
- Copy of the International Search Report filed on 01/24/2006
- Copy of IPE Report filed on 01/24/2006
- Preliminary Amendments filed on 01/24/2006
- Information Disclosure Statements filed on 01/24/2006
- Oath or Declaration filed on 01/24/2006
- Small Entity Statement filed on 01/24/2006
- Request for Immediate Examination filed on 01/24/2006
- U.S. Basic National Fees filed on 01/24/2006
- Priority Documents filed on 01/24/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter

FILE NO: FAK-8011 ATTY: RSW  
DUE DATE: 07-02-2006 ( 20060702 )  
FISHER, ADAMS &/INIT: ( 20060502 )  
ACTION: 10 RES PER: 2 M DK1  
MISSING REQUIREMENTS DUE / 1081

## SUMMARY OF FEES DUE:

Total additional fees required for this application is \$65 for a Small Entity:

- \$65 Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

LAMONT M HUNTER

Telephone: (703) 308-9140 EXT 201

## PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/565,616                  | PCT/AU04/01006                | FAK8011          |